



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,321	04/14/2005	Hiroyuki Ebinuma	270475US0PCT	7005
22850	7590	03/09/2007		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER MI, QIUWEN	
			ART UNIT 1655	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary

Application No.

10/531,321

Applicant(s)

EBINUMA, HIROYUKI

Examiner

Qiuwen Mi

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAIICHIKAKAGU YAKUHHN KK (JP 2001057897) in view of Jones (US 5,741,491).

DAIICHIKAKAGU YAKUHHN KK teaches the production of fructosyl-valine for measuring hemoglobin A1c in diabetes mellitus patient. The method comprises coupling N-terminal valine residue of protein or peptide to fructose to form fructosyl-valine, which is then removed (defructosylating) from the peptide or protein by enzymatic treatment, using serine carboxypeptidase. The method also teaches measuring hemoglobin A1c and glucose (reaction product) level in diabetes mellitus patient (see the Abstract).

DAIICHIKAKAGU YAKUHHN KK does not teach the enzyme is extracted from a plant.

Jones teaches treating diabetes with *Heracleum lanatum* (Umbrelliae family) (col 1, lines 32-38) and measuring HbA1c (the same as hemoglobin A1c, see the instant specification, page 1, 2nd paragraph) and glucose (reaction product) level afterwards (cols 7&8, Tables 7&8). As

Art Unit: 1655

evidenced by Edens et al (US 6,372,282), serine carboxypeptidases occur in fungi and higher plants (col 3, lines 1-5). Therefore, family Umbrelliae contains enzyme serine carboxypeptidases.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use *Heracleum lanatum* (Umbrelliae family) in Jones to defructosylate the fructosylated peptide in DAIICHIKAKAGU YAKUHHN KK since the treatment of extract of *Heracleum lanatum* (Umbrelliae family) in Jones achieved dramatic improvement in glucose control as evidenced by maintaining a lower blood glucose level, a reduced dose of medication (col 4, lines 47-52), an improved blood glucose the HbA1c, and an improved glycemic status (col 6, lines 57-67), one of ordinary skill in the art would have been motivated to make the modifications.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAIICHIKAKAGU YAKUHHN KK (JP 2001057897) in view of Karl et al (EP 598329).

DAIICHIKAKAGU YAKUHHN KK teaches the production of fructosyl-valine for measuring hemoglobin A1c in diabetes mellitus patient. The method comprises coupling N-terminal valine residue of protein or peptide to fructose to form fructosyl-valine, which is then removed (defructosylating) from the peptide or protein by enzymatic treatment, using serine

Art Unit: 1655

carboxypeptidase. The method also teaches measuring hemoglobin A1c and glucose (reaction product) level in diabetes mellitus patient (see the Abstract).

DAIICHIKAKAGU YAKUHHN KK does not teach the fructosylated peptide with an amino acid sequence represented by any of SEQ ID No: 1-5.

Karl et al teach an amino acid sequence that 100% matches with SEQ ID NO. 1. Karl et al also teach that the glycosylated (including fructosylated, see <http://en.wikipedia.org/wiki/Glycosylated>) oligopeptide recognizes glycosylated hemoglobin HbA1c, and therefore provides an indication of blood glucose levels in diabetes mellitus.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the fructosylated peptide with SEQ ID NO. 1. in Karl et al since the glycosylated oligopeptide in Karl et al allows simultaneous detection of three forms of hemoglobin and therefore serves as an indication of long term blood glucose levels for monitoring diabetes, one of ordinary skill in the art would have been motivated to make the modifications.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Art Unit: 1655

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry Mckelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**MICHAEL MELLER
PRIMARY EXAMINER**